



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

AUG - 6 1991

Re: Monopril  
Docket No. 91E-0225

#12

The Honorable Harry F. Manbeck, Jr.  
Assistant Secretary of Commerce  
and Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,337,201, filed by E.R. Squibb & Sons, Inc., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Monopril, the human drug product claimed by the patent.

The total length of the review period for Monopril is 2,710 days. Of this time, 1,797 days occurred during the testing phase and 913 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 16, 1983.

The applicant claims December 14, 1983, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 16, 1983.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: November 15, 1988.

FDA has verified the applicant's claim that the new drug application (NDA 19-915) was filed on November 15, 1988.

3. The date the application was approved: May 16, 1991.

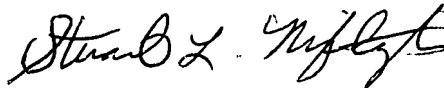
FDA has verified the applicant's claim that NDA 19-915 was approved on May 16, 1991.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Stuart L. Nightingale".

Stuart L. Nightingale, M.D.  
Associate Commissioner  
for Health Affairs

cc: Donald J. Barrack  
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